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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,430	04/30/2001	Jennifer H. Lai	5100-7001 0016-US	4378

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ROBINS & PASTERNAK
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,430

Applicant(s)

LAI ET AL.

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 13-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,13-15,21-29 and 38-42 is/are rejected.
- 7) ☒ Claim(s) 6-10,16-20,30-37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The response filed 11/20/03 has been fully considered and the amendment has been entered. In further consideration of Balch et al (US6,083,763), it appears that Balch et al also does teach the newly incorporated limitation from claim 11 – “is produced by process comprising incorporating the polynucleotide comprising the first label into the amplification product using a polymerase”. As the Balch et al reference was not cited previously claim 11, finality is withdrawn to allow the applicant an opportunity to address the new rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1,3-5, 13-15, 21-28 & 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Balch (US6,083,763 July 4, 2000).

Balch teach a method of multiplexed molecular analysis involving providing an amplification product of a polynucleotide comprising a first label and capture sequence, providing a substrate that is conjugated to a first capture probe, contacting sample with capture

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probe and determining first label is associated with substrate. (see whole doc. col. 35 lines 45-65). Capture probe is a polynucleotide (see col. 17 lines 27-65). They teach glass slides and different wells with glass slides in microplate (see col. 8 line 40, col. 31 lines 31). They teach that the primers have unique universal sequences and complementary to different loci on the template accomplished. (see col. 34 line 43-45). They teach labels such as fluorescein (see col. 34 line 52, col. 32 line 43-45). They teach extension of primer to form amplification product by polymerase (see col. 35 line 43). They teach alkaline phosphatase (see col. 25 line 15). They teach dioxigenin or biotin (see col. 25 line 9). They teach lathanide (LN) chelators (see col. 26 lines 36). They teaching using multiple different labels to different biosites (see col. 32 line 43-46 & fig. 19D). They teach mRNA analytes, DNA , RNA analytes (see col. 8 lines 18-20). They teach testing for plurality of targets including three and four loci and 25 different loci (see figures 14, 15 & 17). They teach detecting SNP (see col. 34 line 19). They teach use of exonuclease to digest non extended primers (see col.34 line 47). Attachment of capture probes may be by 3' or 5' end thru carboxylated derivative (see col. 18 lines 55-67).

The newly incorporated limitation in claim 1 - "is produced by process comprising incorporating the polynucleotide comprising the first label into the amplification product using a polymerase" is met by Balch et al teachings. Specifically, Balch et al teach one primer contains a fluorescently detectable label such as fluorescein (see col. 35 line 52-54 & fig. 15).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (US6,083,763 July 4, 2000) in view of Skouv et al (US6,316,918 Nov. 13, 2001).

The teachings of Balch et al are described previously.

Balch et al do not teach allele detection.

Skouv et al teach detecting and differentiating alleles with primer with labels (see col. 10 line 16-35).

One of ordinary skill in the art would have been motivated to apply Skouv et al's allele detection to Balch et al's PCR method in order to differentiate and capture alleles of gene. Skouv et al teach using different primers' to detect variant nucleic acids using different lables. It would have been prima facie obvious to apply Skouv et al's primers in Balch et al's PCR method in order to distinguish different alleles with labels.

SUMMARY

4. Claims 6-10,16-20,30-37 are objected for depending on rejected claim but are free of the prior art. There is no prior art that teach or suggest the method using comprising a first semiconductor nanocrystal.

CONCLUSION

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

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Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.



JEFFREY SIEW
PRIMARY EXAMINER

December 20, 2003